

EXHIBIT C

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3 IN RE: :SUPERIOR COURT OF

PELVIC MESH/GYNECARE :NEW JERSEY

4 LITIGATION :LAW DIVISION -

:ATLANTIC COUNTY

5 :

:MASTER CASE 6341-10

6 :

:CASE NO. 291 CT

7

CONFIDENTIAL-SUBJECT TO STIPULATION AND ORDER OF

8 CONFIDENTIALITY

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September 12, 2012

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12 Volume I of the transcript of the
13 Deposition of CHARLOTTE OWENS, M.D., called for
14 Videotaped Examination in the above-captioned
15 matter, said deposition taken pursuant to
16 Superior Court Rules of Practice and Procedure,
17 by and before JoRita B. Meyer, a Certified
18 Realtime Reporter, Registered Merit Reporter,
19 and Certified Court Reporter for the State of
20 Georgia, at the offices of Troutman Sanders,
21 600 Peachtree Street Northeast, Atlanta,
22 Georgia, commencing at 9:39 a.m.

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1 little bit before we talk about some specific
2 facts.

3 Okay?

4 A. Okay.

5 Q. Let's start with my understanding
6 from the CV as to your medical education. You
7 went to University of Michigan Medical School,
8 correct?

9 A. Correct.

10 Q. You then did your internship and
11 residency at Henry Ford Health System in the
12 department of obstetrics and gynecology,
13 correct?

14 A. Correct.

15 Q. And that's affiliated with the
16 University of Michigan?

17 A. At the time it was. It no longer is
18 a direct affiliation.

19 Q. After you -- well, rephrase.

20 It says that your residency ended in
21 July of 1999; is that correct?

22 A. Correct.

23 Q. And when you finished your residency,
24 it looks to me like you went into clinical
25 practice in Florida. Is that accurate?

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1 A. Yes.

2 Q. So from 1999 to 2003, you had the
3 general OB-GYN practice that you described to
4 me earlier, correct?

5 A. Correct.

6 Q. And in terms of the types of pelvic
7 floor repairs that you performed, was that
8 consistent between 1999 and 2003?

9 A. Yes.

10 Q. Between 1999 and 2003, other than
11 utilizing Marlex mesh to augment pelvic floor
12 repairs, did you use any other specific mesh
13 products that you can recall as you sit here
14 now?

15 A. I'm sure I -- I'm sure we did, but,
16 again, I can't recall the names at this time.

17 Q. According to your CV, in 2003 you
18 became Worldwide Medical Director at Gynecare;
19 is that correct?

20 A. Yes, it is.

21 Q. And what was it that led you to go to
22 work at Gynecare as Worldwide Medical Director
23 in 2003?

24 A. During the time of my clinical
25 practice, I became a speak -- on the speaker

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1 MS. KABBASH: Okay.

2 THE VIDEOGRAPHER: Going off video
3 record, 9:54 a.m.

4 (Recess)

5 THE VIDEOGRAPHER: And we're back
6 on video record at 10:02 a.m.

7 BY MR. SLATER:

8 Q. Dr. Owens, you went to work at
9 Gynecare in 2003, and you stayed at Gynecare
10 until 2005, correct?

11 A. Correct.

12 Q. Can you give me more specific dates,
13 even if it's just months, within those years
14 that you started and finished?

15 A. I remember it was summertime of 2003,
16 and I left late August of 2005.

17 Q. According to your CV, when you left
18 Gynecare, you went to work at Kimberly-Clark
19 Corporation as Director of Global Clinical
20 Affairs; is that correct?

21 A. Correct.

22 Q. In very, very general, simple terms
23 what was your position? What did that entail
24 at Kimberly-Clark?

25 A. I was responsible for the clinical

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1 I also did some work for the state of
2 Florida, where I reviewed potential cases that
3 were coming against other physicians on behalf
4 of the state.

5 Q. That would be in connection with
6 medical malpractice cases, correct?

7 A. Correct.

8 Q. When you -- when you were on the
9 speaker advisory board at Johnson & Johnson
10 before you joined Gynecare, what types of
11 technologies or products were you consulting
12 with regard to?

13 A. I spoke about their oral
14 contraceptives and they had a hormone
15 replacement therapy line that I also spoke
16 about and I was also a consultant for
17 Ortho Evra, the birth control patch.

18 Q. Before you went to work at Gynecare,
19 would it be fair to say that you didn't
20 consider yourself to be an expert with regard
21 to the use of mesh to treat pelvic floor
22 prolapse?

23 A. I considered myself to be competent
24 but I was not a urogynecologist and so I didn't
25 routinely, you know, have that focus as the

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1 mainstay of my practice, no.

2 Q. And before you joined Gynecare, when
3 you performed pelvic floor repairs on your own,
4 as you told me a little earlier, those would
5 have been native tissue repairs, correct?

6 A. Predominantly native tissue
7 repairs --

8 Q. Okay.

9 A. -- yes.

10 Q. Well, you said that when you would
11 use any sort of a mesh to augment, you would do
12 that in conjunction with one of your
13 partners --

14 A. Sure.

15 Q. -- who you said had a lot of
16 experience using that type of material,
17 correct?

18 A. Correct.

19 Q. Okay. When you went to work at
20 Gynecare -- well, let me -- let me take a step
21 back.

22 How is it that you went to --
23 actually -- well, rephrase.

24 How did you end up getting that job?
25 You said that you had worked on the speaker

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1 Before you went to work at Gynecare,
2 you didn't have any knowledge with regard to
3 the specific physical characteristics of the
4 actual Gynemesh material, correct?

5 A. Correct.

6 Q. You relied on other people within the
7 company as well as potentially others outside
8 the company who consulted to give you
9 information about that, correct?

10 A. That, plus they had some -- some data
11 that they had generated, both in what we'll
12 call preclinical or animal studies, and had
13 also did some R&D analysis of it.

14 So, you know, I want to make sure
15 that it's not like people just tell me and you
16 believe it, that we actually do review
17 information independently in order to make our
18 own final opinion.

19 Q. Okay. As you -- well, rephrase.

20 As time went forward, after you
21 started at Gynecare and Project d'Art was going
22 forward, the feasibility of that project was
23 assessed routinely, correct?

24 A. Correct.

25 Q. In evaluating the feasibility of

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1 education package; so this would be one of the
2 things that they would look to, yes.

3 Q. Do you understand the significance
4 under FDA regulations of the IFU being the
5 primary label for the PROLIFT?

6 A. I understand the FDA regulations
7 around the document. I also understand the way
8 that physicians are trained and operate.

9 MR. SLATER: Move to strike from "I
10 also" forward.

11 BY MR. SLATER:

12 Q. What's your understanding as to the
13 significance of the IFU being the primary label
14 for the PROLIFT from FDA regulatory standpoint?

15 A. That the agency sees this as the
16 document that they review as a part of the
17 packaging for our materials. So it should
18 contain the relevant indications, description,
19 and -- and other pertinent information as
20 prescribed by the regulations.

21 Q. That would also include all necessary
22 contraindications, warnings and precautions,
23 and adverse reactions, correct?

24 A. It would include warnings,
25 precautions, contraindications, adverse

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1 reactions, sterility, disposal, storage,
2 et cetera.

3 Q. You have understood that all of the
4 information in the IFU needed to be accurate,
5 correct?

6 A. Yes.

7 Q. You understood that physicians were
8 going to rely on the IFU in making decisions
9 about whether or not to use the PROLIFT in
10 treating patients, correct?

11 MR. BROWN: Objection.

12 THE WITNESS: Physicians will not
13 rely solely on the IFU for making their
14 decisions. Physicians will use the IFU
15 to help inform them, but they will also
16 use other information.

17 BY MR. SLATER:

18 Q. You understood physicians would rely,
19 at least in part, on the PROLIFT IFU in making
20 decisions about whether they wanted to use that
21 product, that medical device, that system, in
22 their patients, correct?

23 MR. BROWN: Objection.

24 THE WITNESS: Physicians will use
25 this document and other documents to